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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/539,032	06/13/2005	Ken-ichi Inui	4439-4034	8848	
	7590 11/28/2007 FINNEGAN, L.L.P.		EXAMINER		
3 WORLD FINANCIAL CENTER			LI, RUIXIANG		
NEW YORK, NY 10281-2101		ART UNIT	ART UNIT	PAPER NUMBER	
			. 1646		
		·			
	•		NOTIFICATION DATE	DELIVERY MODE	
			11/28/2007	ELECTRONIC	

### Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOPatentCommunications@Morganfinnegan.com Shopkins@Morganfinnegan.com jmedina@Morganfinnegan.com

	Application No.	Applicant(s)					
	10/539,032	INUI ET AL.					
Office Action Summary	Examiner	Art Unit					
	Ruixiang Li	1646					
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address					
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	I. lely filed the mailing date of this communication. O (35 U.S.C. 8 133)					
Status							
1)⊠ Responsive to communication(s) filed on 10/17	7/2007						
	action is non-final.						
·		secution as to the merits is					
,	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	3 3.31 2.3.					
4)⊠ Claim(s) <u>1-29</u> is/are pending in the application.							
4a) Of the above claim(s) <u>4, 5, 7-9, 14-17, 19, a</u>		consideration					
5) Claim(s) is/are allowed.	Ma 21 25 15/are withdrawn north	·					
6) Claim(s) <u>1-3, 6, 10-13, 18, and 20</u> is/are reject	ed						
7) Claim(s) is/are objected to.	cu.						
8) Claim(s) are subject to restriction and/or	election requirement						
Application Papers	ciconon requirement.						
		•					
9) The specification is objected to by the Examiner							
10) $\boxtimes$ The drawing(s) filed on $\underline{06/13/2005}$ is/are: a) $\boxtimes$	, ,						
Applicant may not request that any objection to the o							
Replacement drawing sheet(s) including the correcti							
11) The oath or declaration is objected to by the Exa	aminer. Note the attached Office	Action or form PTO-152.					
Priority under 35 U.S.C. § 119							
12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a)⊠ All b)□ Some * c)□ None of:							
	1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)		÷					
Notice of References Cited (PTO-892)  4) ☐ Interview Summary (PTO-413)							
2) Notice of Traftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	te					
i) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date <u>04/21/2006 &amp; 06/13/2005</u> 5) Notice of Informal Patent Application 6) Other: <u>Sequence alignment.</u>							
Paper No(s)/Mail Date <u>04/21/2006 &amp; 06/13/2005</u> . 6) ☑ Other: <u>Sequence alignment</u> .							

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#### **DETAILED ACTION**

### Election/Restrictions

- 1. Applicant's election of Group I (claims 1-3, 6, 10-13, 18, and 20) and SEQ ID NO: 1 in the reply filed on 10/17/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 2. Claims 1-29 are pending. Claims 1-3, 6, 10-13, 18, and 20 are currently under consideration. All other claims are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

#### Information Disclosure Statement

3. The information disclosure statements filed on 04/21/2006 and 06/13/2005 have been considered by the examiner.

#### **Drawings**

4. The drawings filed on 06/13/2005 are accepted by the Examiner.

## Claim Rejections—35 USC § 101

5. 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. §101 because the claimed invention is directed non-statutory subject matter.

Claims 1-3, as written, do not sufficiently distinguish over a DNA that exists naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "isolated" or "purified". See MPEP 2105.

# Claim Rejections—35 USC § 112, 1st paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3, 6, 10-13, 18, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule encoding the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for the instantly claimed genus of DNA molecules and probes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors that are considered when determining whether a disclosure

satisfies enablement requirement include: (i) the quantity of experimentation necessary; (ii) the amount of direction or guidance presented; (iii) the existence of working examples; (iv) the nature of the invention; (v) the state of the prior art; (vi) the relative skill of those in the art; (vii) the predictability or unpredictability of the art; and (viii) the breadth of the claims. Ex Parte Forman, 230 USPQ 546 (Bd Pat. App. & Int. 1986); In re Wands, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

Claim 1 recites a DNA which comprises a base sequence shown by SEQ ID NO: 1 or its complementary sequence, or a sequence containing part or whole of these sequences, claim 2 recites a DNA which hybridizes with then DNA according to claim 1 under a stringent condition, and which encodes a polypeptide having glucose and/or fructose transporter function, whereas claim 3 recites a DNA which encodes a polypeptide comprising an amino acid sequence wherein one or a few amino acid sequence are deleted, substituted or added in the amino acid sequence of SEQ ID NO: 2. Claims 18 and 20 are drawn to a probe comprising whole or part of an antisense strand of the base sequence of claim 1. Claims 6, 10-13, 18, and 20 depend from claims 1-3, directly or indirectly. There are no structural and functional limitations for the DNA molecules in claim 1. Claims 2 and 3 do not recite a structural limitation for the DNA molecules. Thus, the claims are overly broad.

While providing sufficient guidance and/or working examples with respect to make and use the DNA molecule that encodes the polypeptide of SEQ ID NO: 2, the instant disclosure fails to provide sufficient guidance and/or working examples to make and use the variants or homologues of DNA molecule that encodes the

polypeptide of SEQ ID NO: 2 and the probes comprising part of an antisense strand of the base sequence of claim 1.

It is unpredictable whether a variant or homologue of SEQ ID NO: 2 would retain the same function as that of the full length of polypeptide of SEQ ID NO: 2. The state of the art (See, e.g., Ngo, et al, *The Protein Folding Problem and Tertiary Structure Prediction*, 1994, Merz, et al. (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495) is such that the relationship between sequence of a protein and its activity is not well understood and is not predictable. Excising out portions of a protein or modifications to a protein, e.g., by substitutions or deletions, would often result in deleterious effects to the overall activity and effectiveness of the protein.

Furthermore, the state of the art is such that determining the specificity of hybridization is empirical by nature and the effect of mismatches is unpredictable, as taught by Wallace et al. (Methods Enzymol. 152:432-443, 1987) and Sambrook et al. (Molecular Cloning, A Laboratory Manual, 2<sup>nd</sup> Edition, 1989, Cold Spring Harbor Laboratory, Cold Spring Harbor, NY, page 11.47). It is well known in the art that hybridization yields nucleic acids that are structurally related, but functionally different. Thus, in view of the nature of complexity of the work and unpredictability of the art, it would take undue experimentation for one skilled in the art to make and use the claimed genus of DNA molecules without sufficient guidance, working examples, and knowledge about functions of encompassed DNA molecules structurally related to SEQ ID NO: 1.

It is also noted that claim 20 recites "a pharmaceutical for diagnosing glucose

an/or fructose transporter function". However, the instant disclosure fails to disclose an association of glucose an/or fructose transporter function with any particular diseases. It would take undue experimentation for one skilled in the art to practice the claimed invention.

Accordingly, The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the DNA molecules and probes commensurate in scope with these claims.

9. Claims 1-3, 6, 10-13, 18, and 20 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claim 1 recites a DNA which comprises a base sequence shown by SEQ ID NO: 1 or its complementary sequence, or a sequence containing part or whole of these sequences. Claim 2 recites a DNA which hybridizes with then DNA according to claim 1 under a stringent condition, and which encodes a polypeptide having glucose and/or fructose transporter function. Claim 3 recites a DNA which encodes a

polypeptide comprising an amino acid sequence wherein one or a few amino acid sequence are deleted, substituted or added in the amino acid sequence of SEQ ID NO: 2. Claims 6, 10-13, 18, and 20 depend from claims 1-3, directly or indirectly. Thus, the claims encompass a genus of DNA molecules that are variants and homologues of the DNA that encodes the polypeptide of SEQ ID NO: 2. Claim 1 does not require that the DNA possess any particular biological activity, nor any particular conserved structure, nor other disclosed distinguishing feature. While claims 2 and 3 recite a functional limitation, they do not require that the DNA molecules possess any particular any particular conserved structure nor other disclosed distinguishing feature.

The instant disclosure of the DNA set forth in SEQ ID NO: 1 that encodes a Na+-dependent glucose and fructose transporter in rat kidney set forth in SEQ ID NO: 2 does not adequately support the scope of the recited genus of DNA molecules, which encompasses a substantial variety of homologues or variants of the DNA that encodes the polypeptide of SEQ ID NO: 2. A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). While disclosing the amino acid sequences of SEQ ID NO: 2 and its encoding DNA of SEQ ID NO: 1, the instant disclosure fails to provide sufficient description information, such as definitive

structural or functional features of the recited genus of DNA molecules or the polypeptides encoded by the DNA molecules. There is no description of the conserved regions that are critical to the structure and function of the genus recited. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function.

Moreover, claim 1 encompasses virtually any random nucleic acid sequence of any length as long as it comprises a portion of SEQ ID NO: 1 since the claim does not recite any structural and functional limitations. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed DNA molecules as being identical to those instantly claimed.

Due to the breadth of the claimed genus and lack of the definitive structural or functional features of the claimed genus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus. Accordingly, only the isolated DNA molecule encoding the polypeptide of SEQ ID NO: 2 (including the DNA of SEQ ID NO: 1), but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph.

# Claim Rejections—35 USC§ 112, 2<sup>nd</sup> paragraph

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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11. Claims 1, 2, 6, 10-13, 18, and 20 are rejected under 35 U.S.C. §112, second

paragraph, as being indefinite for failing to particularly point out and distinctly claim

the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it recites a DNA which comprises a base

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sequence shown by SEQ ID NO: 1 or its complementary sequence, or a sequence

containing part or whole of these sequences. It is unclear "its complementary

sequence" is referred to the complementary sequence of SEQ ID NO: 1 or the

complementary sequence of the DNA. In addition, the claim recites "a sequence

containing part of whole of these sequences". It is unclear what 'these sequences"

are referred to.

Claim 2 recites "a stringent condition". However, neither the specification nor

the art provides an unambiguous definition for the term, rendering the claim

indefinite.

Claim 18 is indefinite because it recites "a probe for diagnosing glucose and/or

fructose transporter function". It is unclear what the metes and bounds of the

preamble are. Claim 20 is indefinite because the language is so ambiguous that it is

unclear what is being claimed.

Claims 6 and 10-13 are rejected as dependent claims from claim 1.

Claim Rejections—35 U.S.C. §102 (e)

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Isogai et al. (U.S. Patent No. 6,943,241 B2, September 13, 2005; 102 (e) date: 1/25/2002).

Isogai et al. teach a DNA comprising part of SEQ ID NO: 1 (see attached sequence alignment), meeting the lmitations of claim 1.

### Claim Objections—Minor Informalities

- 14. Claim 6 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n).
- 15. Claims 2, 3, 6, 10-13, 18, and 20 are objected because they recite "and/or".
- 16. Claims 1 and 3 are objected because they use an indefinite article to refer to a unique sequence; "a base sequence shown by SEQ ID NO: 1" in claim 1 should be amended to "the base sequence shown in SEQ ID NO: 1", whereas "an amino acid sequence shown by SEQ ID NO: 2" in claim 3 should be amended to "the amino acid sequence shown by SEQ ID NO: 2".
- 17. Claim 20 is objected to because it recites "A pharmaceutical", which is not complete in meaning.

Appropriate correction is required.

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Conclusion

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18. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875.

The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00

pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the

organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for published

applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For

more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you

have questions on access to the Private PAIR system, please contact the Electronic

Business Center (EBC) at the toll-free phone number 866-217-9197.

Rustiang L.

Ruixiang Li, Ph.D. **Primary Examiner** November 21, 2007

RUIXIANG LI, PH.D. PRIMARY EXAMINER

### Sequence Alignment for 10/539,032

```
Alignment 1
US-10-104-047-1471
; Sequence 1471, Application US/10104047
; Patent No. 6943241
; GENERAL INFORMATION:
  APPLICANT: HELIX RESEARCH INSTITUTE
  TITLE OF INVENTION: No. 6943241el full length cDNA
  FILE REFERENCE: H1-A0105
  CURRENT APPLICATION NUMBER: US/10/104,047
  CURRENT FILING DATE: 2002-03-25
  PRIOR APPLICATION NUMBER:
  PRIOR FILING DATE:
  NUMBER OF SEQ ID NOS: 4096
  SOFTWARE: PatentIn Ver. 2.1
; SEQ ID NO 1471
   LENGTH: 2052
   TYPE: DNA
   ORGANISM: Homo sapiens
US-10-104-047-1471
 Query Match
                      38.5%; Score 837.4; DB 3; Length 2052;
 Best Local Similarity
                     72.2%; Pred. No. 9.7e-239;
                           0; Mismatches 416;
 Matches 1139; Conservative
                                              Indels
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                                                         Gaps
                                                                3:
Qу
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        253 CTGCTTTCCTGGGAATGGGAGTGAGCGCTGCTGTGCTGGGACCCACATTTCCAGACCTGG 312
            Db
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        313 CCAGAAACGTGAACCGGAACATCAGCAGCCTTTCCGAAATCTTCGTGGGCCGAGCCCTCG 372
Qv
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                                         452 CAACAAACGTGAACCGAAATATCAGTAGTCTGTCTTTCATTTTTGTGGGTCGTGCCTTGG 511
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Qу	673	GGGGTACCACAGCATCTGCTCAGAACCACACAGAGCCTCAGTTAGACCGTTCAGCCTTGA	732
Db	812	TGGGTCCGACAGCGTCTGCTGAAAACCACACAGAGTCTGACTTCCATCCTGCACTCA	868
Qу	733	ACCGATCCTTTGAAGCCGCCTCAGACTCTGTGTTGGCGGTACCTGACGACATGAATCTTC	792
Db	869	ACCAATCATCTGATGCTGACTCAGAAGCTCTGTTTGGAGTACCTAATGATAAGAATTTAC	928
Qу	793	TGTGGGCGTACGCTTCCATTGGAACCTATGTTCTAGTACTTTCTGTCTTCCTGTTTGCTC	852
Db	929	TGTGGGCTTATGCTGTTATCGGTACTTACATGTTCTTAGTTTCTGTCATTTTTTTT	988
Qу	853	CATTCTTTAAAAAGAGGTCAAAGCAGAAAAAAATCCGCAGCGTCTGCTCAGGGAGCTCGAA	912
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Db	1049		1108
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Alignment 2
US-10-104-047-3441
; Sequence 3441, Application US/10104047
; Patent No. 6943241
; GENERAL INFORMATION:
  APPLICANT: HELIX RESEARCH INSTITUTE
  TITLE OF INVENTION: No. 6943241el full length cDNA
  FILE REFERENCE: H1-A0105
  CURRENT APPLICATION NUMBER: US/10/104,047
  CURRENT FILING DATE: 2002-03-25
  PRIOR APPLICATION NUMBER:
  PRIOR FILING DATE:
  NUMBER OF SEO ID NOS: 4096
  SOFTWARE: PatentIn Ver. 2.1
 SEQ ID NO 3441
   LENGTH: 518
   TYPE: PRT
   ORGANISM: Homo sapiens
US-10-104-047-3441
 Query Match
                     66.4%; Score 1631.5; DB 2; Length 518;
 Best Local Similarity 73.1%; Pred. No. 3.9e-167;
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Qу
           Db
        300 LSNIGSLTSSLFLVLFDKNPICLWIATSVYGASMATTFPSGVSWIEQYTTIHGKSAAFFV 359
        405 VGAALGLMATPALSGILQGHYPDLPVILYMCLGSAVLTTVLFPVMYKVATLPLDRKOEKS 464
Qу
            360 IGASLGEMAIPAVIGILQGKYPDLPVVLYTSLGASIATGILFPVLYKLATSPLDRQRKED 419
Db
        465 INSEGQKILLSSSRL 479
Qу
             11 11 11111
Db
        420 RKSEDQKALLSSSGL 434
```